REMARKS

Claims 1-46 are pending. Claims 25, 36, 37 and 40 have been amended. Claims 1-15, 22-24, 28-29 and 42-46 have been cancelled without prejudice to or disclaimer of the underlying subject matter. Support for the amended claims can be found throughout the specification and in the claims as originally filed. Upon entry of this amendment, claims 16-21, 25-27 and 30-41 will be pending. In addition, the specification has been amended to remove alleged hyperlinks or other browser-executable form from the specification. No new matter enters by way of these amendments.

I. Election/Restriction

Applicants acknowledge the finality of the restriction requirement. However, Applicants maintain that the restriction of the claims is improper. The Office Action states that the restriction requirement remains proper because "Applicant has not provided any evidence or arguments that the inventions of Groups I-VIII could be examined without a serious burden upon the office becausew [sic] the inventions of Groups I-VIII would each require separate consideration." Office Action at page 2. Applicants respectfully maintain that the Office has not shown that a search and examination of the entire application would cause any burden as argued in Applicant's Response to Restriction Requirement filed September 7, 2004. However, in order to facilitate prosecution, non-elected claims 1-15, 22-24, 28-29 and 42-46 have been cancelled without prejudice to or disclaimer of the underlying subject matter.

II. Information Disclosure Statement

Applicants thank the Examiner for returning signed copies of the Form 1449 for the information disclosure statement filed on March 8, 2002.

III. Objections to the Specification and Claims

The specification has been objected to for purportedly containing "embedded hyperlink and/or other form of browser-executable code." Office Action at pages 2. Applicants have amended the specification to remove the alleged embedded hyperlinks and other forms of browser-executable code (instead listing the websites using the format "available on the worldwide web at 'websitename.html'"). The citation of a website in this format does not offend United States Patent and Trademark Office policy, and should be allowed in an application. In light of these amendments, applicants respectfully request withdrawal of the objection to the specification.

Claims 25, 36, 37 and 40 have been objected to because of alleged informalities. Office Action at page 3. Applicants have amended claims 25 and 36 to remove non-elected material from the claims. In addition, claims 37 and 40 have been amended at the request of the Examiner to recite "consisting" before "of" on line 2 of each claim. As such, Applicant respectfully requests withdrawal of the objection to these claims.

IV. Oath/Declaration

The Examiner requires a new oath or declaration allegedly because the previously submitted "oath or declaration is defective" because "[n]on-initialed and/or non-dated alterations have been made to the oath or declaration." Office Action at page 3.

Applicants will be filing a substitute oath or declaration in compliance with 37 C.F.R. 1.67(a) shortly. Accordingly, Applicants request that the Examiner hold this objection in abeyance pending receipt of the substitute declaration.

V. Rejections under 35 U.S.C. § 112, First Paragraph, Written Description

Claims 21, 25-27 and 30-41 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one of skill in the art that the inventors had possession of the claimed invention at the time the application was filed. Office Action at page 3. Applicants respectfully disagree.

More particularly, the Examiner alleges that "Applicants fail to describe a representative number of nucleic acid sequences from plants that encode a protein having HES1 activity, nucleic acid sequences encoding HES1 proteins, nucleic acid sequences encoding fragments of SEQ ID NO: 33 or fragments of a HES1 protein." Office Action at page 5. Applicants traverse for at least the following reasons.

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). In accordance with this purpose, Applicants need not "describe," in the sense of Section 112, all things that are encompassed by the claims. To contend otherwise would contradict established jurisprudence, which teaches

that a patent may be infringed by technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 U.S.P.Q.2d 1461, 1464 (Fed. Cir. 1989). A related and equally well-established principle of patent law is that claims "may be broader than the specific embodiment disclosed in a specification." *Ralston Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985), *quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981).

The written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics...*i.e.*, complete or partial structure, other physical and or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002). (quoting from Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, 66 Fed. Reg. 1099, 1106 (Jan. 5, 2001)). Applicants have satisfied that test for written description. For example, Applicants have disclosed a structural feature, the nucleotide sequence of SEQ ID NO: 4, as well as the corresponding amino acid sequence encoded thereby, SEQ ID NO: 33. In addition, as the Examiner acknowledges, the specification describes additional nucleic acid sequences obtained from plant sources and the amino acid sequences encoded by SEQ ID NOs: 1, 2, 3, and 4 (SEQ ID NO: 30, 31, 32 and 33). Moreover, the specification describes the identification of these sequences using a nucleic acid sequence encoding HES1 from yeast. *See, e.g.,* Specification at page 61, line 22 through page 62, line 5. These features provide a basis for each and every

nucleic acid molecule in the claimed genus. Moreover, it distinguishes the members of the claimed genus from non-members.

The specification further provides descriptions of constructs comprising such nucleic acid molecules, and methods of preparing such constructs. *See, e.g.,* specification at page 21, line 3 through page 29, line 2. In addition, the specification provides descriptions of plants comprising the constructs as well as methods for transforming the constructs into plant cells. *See, e.g.*, specification page 29, line 3 through page 35, line 23.

Moreover, Applicants note that the sequences of SEQ ID NOs: 30, 31, 32, and 33 as well as the description and HES1 activity of SEQ ID NO: 35 provides sufficient written description support for claim 21, which is directed to a substantially purified nucleic acid molecule which encodes a plant HES1. Furthermore, these plant sequences have been disclosed as having the capability of modulating sterol content in a plant. Therefore, the specification provides adequate written description support across the scope of all encoding nucleic acids.

As such, Applicants submit that for the foregoing reasons, one of ordinary skill in the art would recognize that at the time of filing Applicants were in possession of the claimed invention. Therefore Applicants respectfully request reconsideration and withdrawal of the written description rejection of claims 21, 25-27 and 30-41 under 35 U.S.C. §112, first paragraph.

VI. Rejections under 35 U.S.C. § 112, First Paragraph, Enablement

Claims 16-21, 25-27 and 30-41 stand rejected under 35 USC § 112, first paragraph, as allegedly containing "subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." Office Action at page 5. This rejection is respectfully traversed for at least the reasons which follow.

The Office Action asserts that "[g]iven the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state of the art..., undue experimentation would be required to practice the claimed invention." *Id.* at page 9. Applicants respectfully disagree.

The specification provides ample disclosure to enable a skilled artisan to make or use the claimed invention. For example, the specification describes multiple plant nucleic acid sequences, and complements thereof, encoding HES1 (including SEQ ID NO: 4), as well as the encoded amino acid sequences (including SEQ ID NO: 33) and fragments thereof. *See, e.g.*, specification at page 12 line 10 through page 18, line 27, page 18, line 29 through page 21, line 2, and in the Sequence Listing. In addition, the specification provides guidance for the preparation of constructs for use in plant transformation methods, as well as methods for the transformation of plants using the constructs. *See, e.g.*, Specification at page 21, line 3 through page 35, line 23.

Moreover, the specification provides examples of sequences encoding HES1 and methods for assaying gene function. *See, e.g.*, Example 1 at pages 60-61. Furthermore, Section 2164.02 of the MPEP states that "[c]ompliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed." An

invention need not be actually reduced to practice prior to filing. *Gould v. Quigg*, 822 F.2d 1074, 1078 3 U.S.P.Q.2d 1302, 1304 (Fed. Cir. 1987). An application disclosure provides sufficient enabling support if one of skill in the art can, using the state of the art and Applicant's written disclosures, practice the invention in its full scope without undue experimentation. *See In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988); *John Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998).

The specification discloses sufficient guidance to allow the skilled artisan to practice the claimed invention without undue experimentation. *See, e.g.*, Specification at page 4, lines 13-21 (describing the class of oxysterol-binding proteins, including HES1), page 12, line 10 through page 13, line 17 (describing fragments of nucleic acid sequences encoding plant HES1 proteins), page 11, lines 13-18 (describing the use of the nucleic acid molecules of the present invention to modulate sterol content in organisms), and page 21, line 3 through page 36, line 7 (describing construct preparation and methods for transforming plants). As such, the specification provides ample guidance to the skilled artisan to make or use the nucleic acid molecules, as well as the methods of producing plants having such nucleic acid molecules and the plants having such nucleic acid molecules as presently claimed.

That *some* experimentation would be required to make and use the invention does not defeat enablement. Section 2164.06 of the MPEP states that "[t]ime and difficulty of experiments are not determinative if they are merely routine." "'The test is not merely quantitative, since a considerable amount of experimentation is possible, if it is merely routine, *or if the specification in question provides a reasonable amount of guidance with*

respect to the direction in which experimentation should proceed." M.P.E.P. § 2164.06 (emphasis added), quoting *In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988) (citing *In re Angstadt*, 537 F.2d 489, 502-04, 190 USPQ 214, 217-19 (CCPA 1976)). As shown above, the specification provides more than a reasonable amount of guidance to make or use the invention as claimed.

The Examiner argues that the "state of the art for computer analysis of nucleic acid sequences is unpredictable because there are a number of inaccuracies that arise when attempting to make function predictions for DNA sequence that have no known function other than that based on homology." Office Action at page 7. The Office cites several references to support the general assertion of some unpredictability of predicting function based on sequence homology. *Id.* at pages 7-9. The Examiner has provided references supporting only some general controversy in the art regarding homology, but has not provided any support for the proposition that the claimed nucleic acid molecules do not encode HES1 proteins; or that one skilled in the art would doubt that the claimed nucleic acid molecules work for the utilities disclosed in the present specification. A broad assertion of "unpredictability" in the art is not sufficient to reject the claimed invention for lack of utility.

The Examiner further cites Fang, *et al.* for the proposition "that there is a lack of functional relatedness among yeast OSBP homologs that includes HES1, and that HES mutants in yeast alone or in combination with other OSBP mutations did not restore growth as did the KES1 homologs," and based on this suggests that "HES1 alone would not produce a detectable phenotype in a transformed plant." Office Action at page 9. Applicants disagree with the Examiner's characterization of the reference. Fang *et al.*

suggest "a lack of functional relatedness among the OSBP homologs of yeast *with regard to genetic interaction with the Sec14p pathway*," and the results indicate "a specificity for the involvement of Kes1p in the negative regulation of Golgi-derived transport vesicle biogenesis." Fang *et al.* at page 6449, second column, first full paragraph (emphasis added). Nothing in Fang *et al.* suggests that the HES1 proteins encoded by the nucleic acid sequences of the present invention could not be used to modulate phytosterol biosynthesis in a plant cell. The Examiner's reliance on Fang *et al.* is misplaced.

The Examiner finally argues that the "Applicant has not performed the most routine of scientific procedures known in the art." Office Action at page 9. It is well established that Applicant needs not teach "conventional and well-known genetic engineering techniques" (*see, e.g., Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000)), which would include, as the Examiner admits, functional complementation procedures. Applicant submits the Examiner has not met the required burden.

Accordingly, for at least these reasons, the enablement rejection under 35 USC § 112, first paragraph, is traversed, and reconsideration and withdrawal of this rejection is respectfully requested.

Conclusion

In view of the foregoing remarks, Applicants respectfully submit that the present application is now in condition for allowance, and notice of such is respectfully requested. The Examiner is encouraged to contact the undersigned should any additional information be necessary for allowance.

Respectfully submitted,

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